CACCP

Confinement Analysis and Critical Control Points Approach to PMP Production

Confinement Analysis and Critical Control Points (CACCP)

- An approach to confinement of PMP material modeled on the Hazard Analysis and Critical Control Points (HACCP) approach used in the food and pharma industries
- Some common elements with other risk assessment/management methodologies such as Zurich hazard analysis

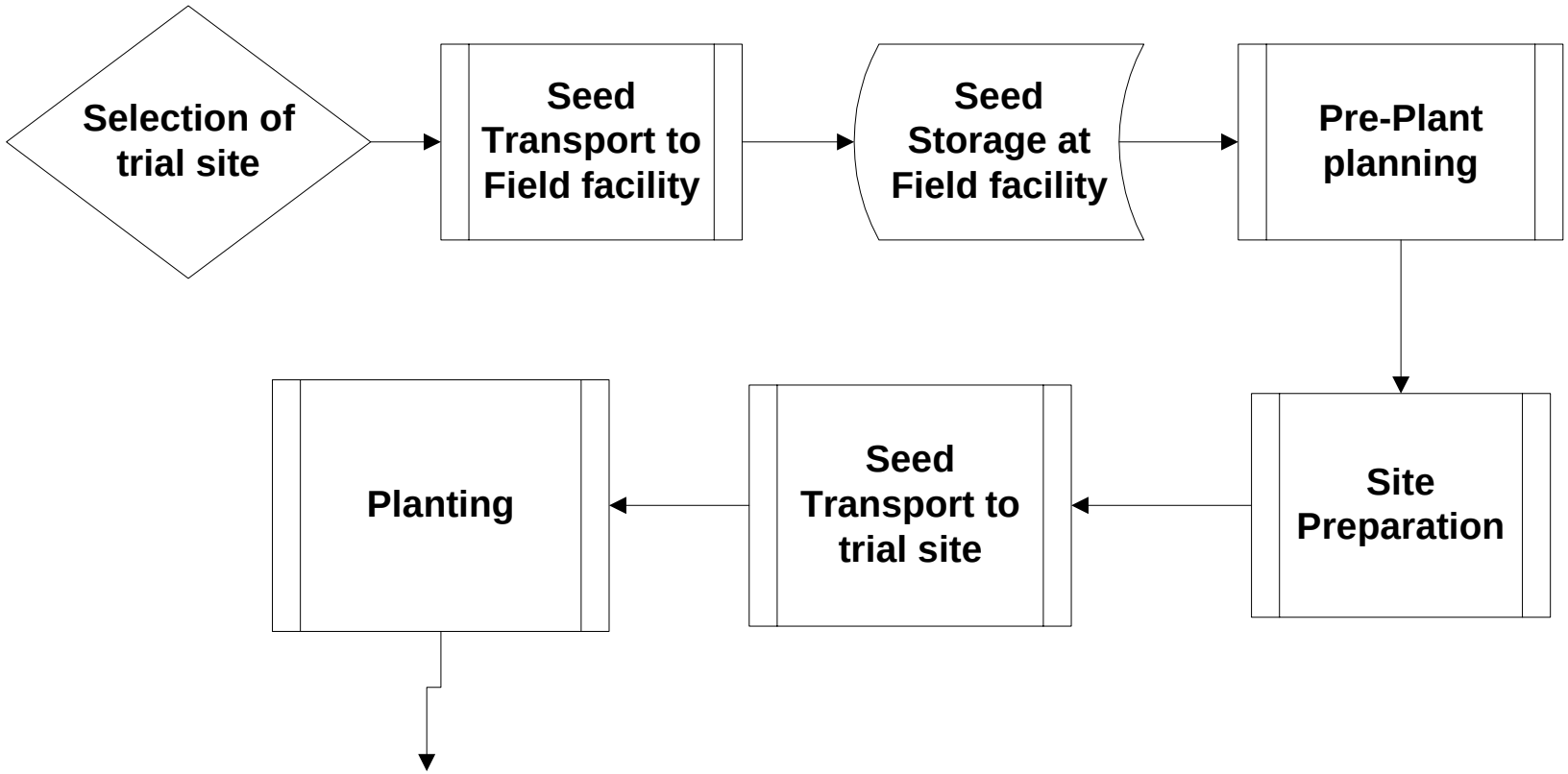
7 Principles

- Conduct loss of confinement analysis
- Determine critical control points
- Establish critical limits
- Establish monitoring procedures
- Establish corrective actions
- Establish verification procedures
- Establish record keeping and documentation

Overview of CACCP process

- Assemble CACCP team
  - Multidisciplinary group with specific knowledge and expertise relevant to product/process
- Describe product, distribution, intended use
- Develop Process flow map and verify
- The CACCP team analyses each of 20 high level operation steps of the process flow map from the perspective of the 7 principles

Process Map


Selection of trial site
Seed Transport to Field facility
Seed Storage at Field facility
Pre-Plant planning
Site Preparation
Seed Transport to trial site
Planting

Confinement analysis

- Identify loss of confinement scenarios/control measures for each step of process map
- Scenario evaluation-severity /likelihood
- Identification of process modifications/improvements
- Provides basis for identification of critical control points

Determine critical control points

- A step at which control can be applied and is essential to prevent or reduce loss of confinement
- Identified using decision tree
- Example: flowering step and possible loss of containment via cross-pollination

Critical process parameters

- Critical process parameter is a process parameter that must be maintained within proscribed limits (critical limits) to achieve the desired quality outcome
- There may be more than one CPP for a process step
- Examples:
  - isolation distance
  - Bee netting

Critical Limits

- Critical limits are upper and/or lower boundaries within which the CPP must be maintained
- Example: 200m minimum isolation distance

Monitoring procedures

- Critical control points must be monitored to ensure that process parameters are within the appropriate range.

Corrective action

- Predetermined response to deviation of Critical Process Parameter outside the acceptable range or lack of adequate control at a Critical Control Point

Verification

- Initial validation of plan to determine that it is scientifically and technically sound
- Periodic auditing to ensure plan is being followed
- Review of plan, CCP monitoring records and corrective action records

Record Keeping and Documentation

- Documentation should include:
  - Summary of the CACCP analysis
  - The CACCP plan
  - All records generated during operation
    - Monitoring record, corrective actions etc
  - place holder

Factors for success

- Commitment from management to the CACCP process
- Pre-requisite programs/ practices, examples
  - cGMP or other QA systems
  - Facilities standards
  - Supplier control
  - Cleaning and sanitation practices
- Education and training

Useful references

- “Hazard Analysis and critical control points principles and applications guidelines”, National Asdvisory committee on microbiological criteria for foods (http://www.cfsan.fda.gov/~comm/nacmcfp.html)
- “HACCP: A process validation tool for ensuring quality of biotech and pharmaceutical products”

  Vega-Mercado et al, BioProcess International May 2003 pages 50-57